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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,661	10/28/2003	Gerald Czygan	117163.00094	4060

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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

NOTIFICATION DATE	DELIVERY MODE
02/06/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/695,661	CZYGAN, GERALD	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,8,28,30,40,43,46,47,50-52,55-57 and 60-62* is/are rejected.

7)☒ Claim(s) *9-17,32,34,35,38,39,42,45,49,54,59 and 64* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,3-5,8-17,28,30,32,34,35,38-40,42,43,45-47,49-52,54-57,59-62 and 64.

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on November 26, 2007. Claims 1, 3-5, 8-17, 28, 30, 32, 34, 35, 38-40, 42, 43, 45-47, 49-52, 54-57, 59-62 and 64 are currently pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. ***Claims 1, 3, 4, 8, 40, 43, 46, 47 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi et al. (U.S. 6,141,585) (herein Prutchi) in view of Meier (EP 1,062,979 A2).*** The Examiner notes that reference to the English version of Meier (U.S. 6,522,924) is made within the following rejections.

4. As to Claims 1 and 50, Prutchi discloses a cardiac stimulator, read as a device 400 for delivering electrical stimulation pulses to body tissue through unipolar and/or bipolar electrode configurations. The device 400 comprises atrial tip electrode 410, atrial ring electrode 420, ventricular tip electrode 440, ventricular ring electrode 450 and can electrode 401 (see Prutchi Abstract, Figs. 4-5, column .7, lines 15-32 and lines 65-67 and column 8, lines 1-45). Prutchi discloses that any of the probable unipolar or bipolar electrode configurations discussed with reference to Fig. 4 are synonymous with the stimulation electrode 520 discussed with reference to Fig. 5 (see Prutchi column 10, lines 6-14). The device 400 of Prutchi further comprises a reservoir

tank capacitor, read as energy storage means C_T for providing electrical stimulation energy to the stimulation electrode 520 from a voltage source, read as an energy source V_i. The device 400 further comprises a charging switch, read as a first switch SW1 with which the energy storage means C_T is switchably connected to the energy source V_i for charging the energy storage means C_T (see Prutchi column 9, lines 20-53). The device 400 of Prutchi further comprises a lead, read as an electrode connection 505 for connecting the stimulation electrode 520 to the device for delivering electrical stimulation pulses to body tissue and a pacing switch, read as a second switch SW2 with which the energy storage means C_T is switchably connected to the electrode connection 505 for delivery of a stimulation pulse via electrode 520 (see Prutchi column 9, lines 53-62).

Prutchi further discloses a discharge switch, read as a short-circuit switch SW3 with which the electrode connection 505, after delivery of the stimulation pulse is switchably connected to a ground potential (see Prutchi Fig. 5) such that, in the case of a connected and implanted electrode 520 a capacitance can be discharged by way of the body tissue, where the capacitance includes at least one Helmholtz capacitance C_L produced on the surface of the stimulation electrode in conjunction with surrounding body fluid or body tissue. The device 400 further comprises a processor, read as a control unit 470 which is connected to at least the first switch SW1, the second switch SW2 and the short-circuit switch SW3 for switching the respective switches and which is adapted to separate the electrode connection 505 from the energy storage means C_T after delivery of the stimulation pulse and at least indirectly connect the electrode connection 505 to the ground potential (see Prutchi Figs. 3A-3B, column 3, lines 5-67, columns 4-5, column 6, lines 1-52, column 9, lines 20-67 and columns 10-12). Prutchi discloses the claimed invention as previously discussed except that it is not specified that the device 400 further comprise a means for monitoring stimulation outcome between 0 milliseconds and 10 milliseconds after delivery of the stimulation pulse that is

connected to the electrode connection 505 and is adapted to detect a drop in voltage over time at the capacitance or a rise in short-circuit current over time at the capacitance, either being representative of a characteristic drop in a myocardium impedance of the body tissue indicating stimulation success.

Meier, however, discloses a capture-detection cardiac pacemaker that automatically and reliably detects stimulation success immediately following application of an electrical stimulation pulse 16 by the pacemaker in order to assure therapeutic efficacy quickly while maximizing the life of the pacemaker's battery or power source (see Meier Fig. 3, Abstract, column 1, lines 5-38, column 2, lines 63-67, column 3, lines 1-19 and column 4, lines 13-35). The method of Meier is additionally advantageous because non-capture or capture can be detected within 2 and 10 milliseconds after delivery of the pacing pulse 16, which is early enough to permit a backup pacing pulse to be delivered immediately, if desired, without the patient noticing, without disturbing the cardiac cycle and without subjecting the patient to "skipped beats". The improved pacemaker (see Meier Fig. 1) comprises an impedance analyzer unit 9, a control unit 4 and a sensor means 5, collectively read as a means for monitoring stimulation outcome between 0 milliseconds and 10 milliseconds after delivery of stimulation pulse 16 by a pulse generator 3 and a stimulation electrode 2. The means for monitoring stimulation outcome of Meier is also specified, in one embodiment, to use the same electrode connection that delivered the stimulation pulse 16 and is adapted to subsequently detect a drop in voltage over time at the capacitance of the electrode connection, the drop in voltage representative of a characteristic drop in a myocardium impedance of the body tissue, indicating stimulation success (see Meier column 1, lines 45-55, column 3, lines 20-61, column 4, lines 1-12; column 5, lines 5-67, column 6, lines 1-55 and column 7, lines 4-37). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device 400 of Prutchi, such that it comprises a means for monitoring stimulation outcome, between 0 milliseconds

and 10 milliseconds after delivery of a stimulation pulse, the means for monitoring connected to the electrode connection 505 and adapted to detect a drop in voltage over time, the drop in voltage representative of a characteristic drop in myocardium impedance, as taught by Meier, such that stimulation success may be immediately and assuredly verified by the device using the same electrode connection 505 in order to quickly assure therapeutic efficacy without the patient noticing any needed delivery of a back-up pacing pulse, without disturbing the patient's cardiac cycle, and without subjecting the patient to "skipped beats" while also maximizing the life of the device's energy source V_i.

5. As to Claims 3 and 4, in addition to the arguments previously presented, Prutchi further discloses that the capacitance also comprises a DC blocking capacitor, read as a coupling capacitor C_B that is connected between the electrode connection and the ground potential when the short-circuit switch SW3 is closed. Prutchi further discloses that the coupling capacitor C_B is arranged between the energy storage means C_T and the electrode connection in such a way that the coupling capacitor C_B is connected in series with the energy storage means C_T when the second switch SW2 is closed (see Prutchi Fig. 5).

6. As to Claim 8, in addition to the arguments previously presented, Meier expressly discloses that the control unit 4 of the stimulation outcome monitoring means further comprises a differentiating member for differentiating the impedance pattern derived by the impedance analyzer 9 from the measured voltage drop in order to analyze the slow variations of the myocardial impedance pattern such that the pacemaker may be adapted to slowly varying boundary conditions (see Meier column 5, lines 41-67 and column 6, lines 1-12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the device 400 of Prutchi in view of Meier such that the means for monitoring stimulation outcome further comprises a differentiating

member for differentiating the impedance pattern derived from the measured voltage drop at the tissue in order to provide a device 400 adapted to slowly varying boundary conditions. The modified Prutchi reference does not disclose expressly that the differentiator differentiate the detected voltage drop. At the time the invention was made, however, it would have been an obvious matter of design choice to a person of ordinary skill in the art to include a differentiating member to differentiate the detected voltage drop because Applicant has not disclosed that such a member provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the device as taught by Prutchi in view of Meier, and Applicant's invention, to perform equally well with either a member for differentiating the impedances derived from the detected voltage drop taught by the modified Prutchi reference or the claimed member for differentiating the detected voltage drop because both measurements perform the same function of ascertaining variations of the myocardial impedance pattern for stimulation success monitoring equally well considering the direct relationship between measured voltage drops across myocardial tissue and calculated impedance drops across myocardial tissue. Therefore, it would have been prima facie obvious to modify the device of Prutchi in view of Meier to obtain the invention as specified in Claim 8 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art.

7. As to Claims 40 and 43, the pacemaker of Meier further comprises a timer within control unit 4 for ascertaining a time delay between the stimulation pulse 16 and a successful stimulation of the heart (i.e. detection of a stimulation outcome) in order to provide a means for the control unit 4 to cause setting of a strength of the stimulation pulse in dependence on the measured delay. Meier expressly discloses that the control unit 4 is responsive to the measured time delay for automatic threshold adaptation/optimization of the stimulation pulse 16 (see Meier column 4, lines 36-42,

column 7, lines 24-31 and column 8, lines 52-56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Prutchi in view of Meier, such that, in order to maintain capture, the means for monitoring stimulation outcome includes a timer for measuring the time duration between delivery of the stimulation and the occurrence of the stimulation outcome and further such that that the control unit receives the measured duration in order to automatically optimize the strength of the stimulation pulse.

8. As to Claims 46, 47, 51 and 52, in addition to the arguments previously presented, Prutchi discloses that in the unipolar electrode configurations, the ground potential of the device 400 includes a housing of the device or a surface portion thereof (see Prutchi Fig. 3B and column 3, lines 5-65).

9. ***Claims 5, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi in view of Meier as applied to Claims 1, 3 and 4 above, and further in view of Lewyn et al. (U.S. 4,114,627) (herein Lewyn).*** The previously modified Prutchi reference discloses the claimed invention as previously discussed except that it is not specified that the device include a means for monitoring stimulation output include a means for detecting the voltage at the coupling capacitor. Lewyn, however, teaches that it is well known in the art of implantable pacer systems to include a means for measuring a residual voltage remaining on discharge coupling capacitor C1 such that an input coupling capacitor C3 of the pacer system's sense amplifier 20 (i.e. a sense output amplifier that senses stimulation outcome after delivery of a stimulation pulse) may be charged to a voltage sufficient to offset the residual voltage of coupling capacitor C1 in order to avoid overloading of the amplifier 20 (see Lewyn Fig. 1, column 6, lines 21-68, column 7, lines 1-64, column 8, lines 12-30 and column 9, lines 9-68, column 10 and column 11, lines 1-12). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Prutchi in view of Meier, such that the means for monitoring stimulation

outcome, including the sense amplifier 62 of capture sense signal processor 58 and a microprocessor 20, include a means for measuring residual voltage charge remaining on the coupling capacitor, as taught by Lewyn in order to avoid overloading the means for monitoring stimulation outcome after delivery of a stimulation pulse.

10. ***Claims 55-57 and 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi in view of Meier as applied to Claims 1, 40, 43, 46, 47 and 50-52 above, and further in view of Paul (U.S. 5,713,931).*** The previously modified Prutchi reference discloses the claimed invention as previously discussed except that it is not specified that the energy source V_i include a charge pump. Paul, however, teaches that it is well known in the art for an implantable pacemaker 10 to include a charge-pump voltage multiplier 48 providing a means to multiply or otherwise step up a voltage provided by a typical battery 46 to a reservoir tank capacitor 54 for providing the appropriate amount of voltage multiplication necessary to produce a pacing pulse which corresponds to pacing amplitude defined by a microprocessor 14 of the pacemaker 10, irrespective of battery 46 depletion (see Paul column 2, lines 5-13, column 3, lines 7-15 and lines 62-67 and column 4, lines 1-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Prutchi in view of Meier, to include a charge pump as taught by Paul, for providing the appropriate amount of voltage multiplication necessary to produce a pacing pulse irrespective of battery depletion.

Allowable Subject Matter

11. Claims 9-17, 32, 34, 35, 38, 39, 42, 45, 49, 54, 59 and 64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

12. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

Benzing, III et al. (U.S. 4,245,643) disclose sampling and holding the instantaneous voltage that exists across an electrical circuit formed by an electrode and heart at the onset of a stimulation pulse generated by a pacemaker for deriving the contact resistance of the electrode attached to the heart tissue. ***Bush et al. (U.S. 6,304,781)*** disclose an electrostimulator comprising a means for monitoring stimulation outcome, between 0 milliseconds and 10 milliseconds after delivery of a stimulation pulse, connected to an electrode interface that is adapted to detect a drop in voltage over time at capacitances of the electrode interface or a rise in a short-circuit current over time at the capacitances of the electrode interface. ***Condie et al. (U.S. 5,843,137)*** teach that the voltage differential arising from the conduction of an excitation current pulse through tissue is directly proportional to the impedance of the tissue. ***Hudrlik (U.S. 5,233,985)*** discloses the use of an operational amplifier output circuit that delivers current through a virtual load to a probe electrode interface where the same amplifier circuit is also used to quickly perform capture detection by immediately measuring the magnitude of the voltage drop induced at the probe electrode interface (within 10 milliseconds or less). ***Lindgren (U.S. 6,238,419)*** teaches the use of a circuit that determines if stimulation outcome does or does not include a fusion or pseudofusion heartbeat based on whether or not measured impedance falls within a predetermined impedance range. ***Park et al.***

(U.S. 5,800,467) disclose a pacing system comprising a controller that induces the leads to deliver an impedance measurement pulse to the right ventricle of the heart during at least a 15 millisecond interval during a window of time following the delivery of a pacing pulse. ***Routh et al. (U.S. 5,766,230)*** disclose a pacemaker that checks for stimulus success while a stimulus pulse is being delivered to the heart. ***Wang et al. (U.S. 5,033,473)*** teach the use of well-known mathematical equations generally used to determine if a waveform decays exponentially for discriminating pace pulse tails generated by signals discriminated from QRS complexes.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jessica L. Reidel/
Patent Examiner, Art Unit 3766
January 28, 2008

Carl H. Layno
CARL LAYNO
PRIMARY EXAMINER